

REMARKS

In the Final Office Action dated May 15, 2009, the Examiner rejected claims 1-4, 6-12, 18, 19, 21-26, 27, 29, 31, and 34 under U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,053,003 to Dadson et al. ("*Dadson*") in view of U.S. Patent No. 4,999,885 to Lee ("*Lee*"); rejected claims 5, 13, 15-17, 20, 30, 32, and 33 under U.S.C. § 103(a) as being unpatentable over *Dadson* in view of *Lee*, and further in view of U.S. Patent No. 5,820,582 to Keilman ("*Keilman*"); rejected claim 14 under U.S.C. § 103(a) as being unpatentable over *Dadson* in view of *Lee*, and further in view of U.S. Patent No. 4,772,497 to Maasola ("*Maasola*"); and rejected claim 35 under U.S.C. § 103(a) as being unpatentable over *Dadson* in view of *Lee*, and further in view of U.S. Patent Publication No. 2002/0115795 to Shang et al. ("*Shang*").

By this Amendment, Applicant has amended claim 21 to more clearly recite the invention. No new matter has been added. Claims 1-35 are currently pending in this application.

REJECTION UNDER § 103(a)

The Examiner rejected claims 1-4, 6-12, 18, 19, 21-26, 27, 29, 31, and 34 under U.S.C. § 103(a) as being unpatentable over *Dadson* in view of *Lee*. Applicant respectfully traverses this rejection at least because the cited references do not disclose or suggest the elements of independent claims 1 and 27.

Applicant maintains that neither *Dadson* nor *Lee* discloses or suggests "organizing means configured to organize the line set within the package during sterilization such that no part of the line set extends across another part of the line set during sterilization of the package" (emphasis added), as recited in independent claim 1.

Dadson discloses “a stem CB, and two arms AB and BD.” (Col. 4, lines. 53-54.)

Dadson also discloses a “connector 60 [that] mates with the patient’s catheter connector.” (Col. 5, lines. 66-67.) *Dadson* further discloses that “[o]ne form of this invention is constituted by a package which contains the “Y” set.” (Col. 5, lines. 61-62.)

Lee discloses “[a] clip for orderly arrangement and identification of flexible lines such as hospital intravenous tubing [that] has a pocket for grasping the tubing and interengaging protrusions and engagement holes whereby the clip can be chained in a line with other similar clips.” (Abstract.)

The Examiner contends that “the clip of *Lee* defines the disposition of the tube elements within the same plane that provides the condition of reciprocal non-crossing of the tubular elements, and therefore the clip of *Lee* is fully capable of being arranged to organize the line set such that no part of the line set extends across another part of the line set (See Figs. 7-10).” (Office Action at 2.)

Even assuming that the clip of *Lee* is “capable” of being arranged according to Applicant’s invention, *Lee* does not in fact, teach, disclose, or suggest “that no part of the line set extends across another part of the line set,” as recited in independent claim 1. As seen in Fig. 7, a clip of *Lee* only prevents crossing of the tubes at a single location (i.e., the location of the clip). Tubes secured by a clip of *Lee* could cross at a location up or down the line from the clip. In fact, by asserting that the clip of *Lee* is only “capable” of being arranged according to Applicant’s invention, the Examiner essentially concedes that this element of Applicant’s claim is not disclosed or taught by the cited references. Applicant submits that just because one or more elements of the prior art

could be arranged to achieve Applicant's invention does not make such a combination or arrangement inherent or obvious.

Furthermore, even assuming that the Examiner's assertion that the capability of creating a claim element based on prior art elements indicates disclosure of said claim element is true, which Applicant rejects, Applicant submits that the Examiner's combination of *Lee* and *Dadson* is based on impermissible hindsight. As stated in M.P.E.P. 2142, "impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art." (Emphasis added.) In the Office Action, the Examiner states that combining *Lee* with *Dadson* "would provide the organizing of the tubing package for use in a peritoneal dialysis treatment in the safety mode." (Office Action at 6.) As an initial matter, it is unclear what the Examiner means by "the safety mode." Furthermore, the Examiner has failed to explain why "organizing of the tubing package for use in a peritoneal dialysis treatment in the safety mode" would lead one of ordinary skill in the art at the time of the invention to combine *Lee* with *Dadson* to arrive at a package where "no part of the line set extends across another part of the line set during sterilization of the package." A line set within a package that had a line that extended across another line would still be "safe," however, such a line set would not meet the above-mentioned element of independent claim 1. Moreover, because neither *Dadson* nor *Lee* discloses sterilization of the claimed tubing package, one of skill in the art at the time of the invention would not have looked to either of these references to solve the problem of sterilizing a tubing package as solved by the invention recited in independent claim 1. Accordingly, Applicant submits that the Examiner's combination of *Lee* and *Dadson* is based on impermissible hindsight.

Moreover, one of skill in the art would not have been motivated to combine *Dadson* and *Lee* to obtain the claimed invention.

For at least the aforementioned reasons, the Examiner has failed to establish a case of prima facie obviousness with respect to independent claim 1. Accordingly, Applicant submits that independent claim 1 is allowable and respectfully asks the Examiner to withdraw the § 103(a) rejection of the claim. Claims 2-4, 6-12, 18, 19, and 21-26 are allowable at least due to their dependence from allowable independent claim 1 and due to their additional recitations of patentable subject matter. Thus, Applicant respectfully requests that the § 103(a) rejection of these claims be withdrawn as well.

Similar to independent claim 1, independent claim 27 recites, among other things, "the step of organizing the line set within the package such that no part of the line set extends across another part of the line set during sterilization of the package." Accordingly, independent claim 27 is allowable over *Dadson* and *Lee* for at least the same reasons as presented above with respect to independent claim 1. Claims 27, 29, 31, and 34 are allowable at least due to their dependence from allowable independent claim 1 and due to their additional recitations of patentable subject matter. Thus, Applicant respectfully requests that the § 103(a) rejection of these claims be withdrawn.

The Examiner rejected claims 5, 13, 15-17, 20, 30, 32, and 33 under U.S.C. § 103(a) as being unpatentable over *Dadson* in view of *Lee*, and further in view of *Keilman*.

Keilman discloses:

a solution bag (10) and a drain bag (12) for a system used for a peritoneal dialysis procedure. . . . A tubing set (16) connects the two filled bags (10,12) and may also be filled with solution (14) which is added to the bags (10,12) and the

tubing set (16) during the manufacturing process. The tubing set (16) is sandwiched between the solution bag (10) and the drain bag (12) and subsequently packaged in an overpouch (24). The method for forming the package including the bags filled with solution is simplified and the overall package size is reduced due to the sandwiched tubing set (16) between the solution bags (10,12) and the provision of solution in both bags (10,12).

(Abstract.) As can be seen in Figs. 1 and 2, the tubes in tubing set 16 of *Keilman* extend over each other in several locations. Accordingly, *Keilman* does not disclose or suggest “organizing means configured to organize the line set within the package during sterilization such that no part of the line set extends across another part of the line set during sterilization of the package” (emphasis added), as recited in independent claim 1 or “the step of organizing the line set within the package such that no part of the line set extends across another part of the line set during sterilization of the package” (emphasis added), as recited in independent claim 27.

In fact, if the package of *Keilman* were sterilized by means of steam autoclave sterilization at a temperature of about 120° C, the areas where the tubes crossed (i.e., where one tube was lying on top of another tube) would be at risk of deforming. Accordingly, *Keilman* does not overcome the above-mentioned deficiencies of *Dadson* and *Lee*. Accordingly, claims 5, 13, 15-17, 20, 30, 32, and 33 are allowable at least due to their dependence from allowable independent claim 1 or 27 and due to their additional recitations of patentable subject matter. Thus, Applicant respectfully requests that the § 103(a) rejection of these claims be withdrawn.

The Examiner also rejected claim 14 under U.S.C. § 103(a) as being unpatentable over *Dadson* in view of *Lee* and *Maassola*. *Dadson*, *Lee*, and *Maassola*

do not disclose or suggest each and every limitation of the rejected claim. The Examiner contends that *Maassola* teaches “the bag for medical solutions made of a mixture of polyolefin and an elastomer.” (Office Action at 21.) *Maassola*, however, does not disclose “organizing means configured to organize the line set within the package during sterilization such that no part of the line set extends across another part of the line set during sterilization of the package,” as recited in independent claim 1. Therefore, *Maassola* does not overcome the above-mentioned deficiencies of *Dadson* and *Lee*. Accordingly, claim 14 is allowable at least due to its dependence from an allowable independent claim 1 and due to its additional recitations of patentable subject matter. Thus, Applicant respectfully requests that the § 103(a) rejection of this claim be withdrawn.

The Examiner rejected claim 35 under U.S.C. § 103(a) as being unpatentable over *Dadson* in view of *Lee* and *Shang*. *Dadson*, *Lee*, and *Shang* do not disclose or suggest each and every limitation of the rejected claim. The Examiner contends that *Shang* teaches “the step of placing (exposing) the tube set in a steam autoclave.” (Office Action at 22.) *Shang*, however, does not disclose “the step of organizing the line set within the package such that no part of the line set extends across another part of the line set during sterilization of the package,” as recited in independent claim 27. Accordingly, *Shang* fails to overcome the deficiencies of *Dadson* and *Lee*. Thus, claim 35 is allowable over the cited references at least due to its dependence from allowable independent claim 27 and its recitations of additional patentable subject matter. Applicant respectfully asks the Examiner to withdraw the rejection of claim 35.

CONCLUSION

In view of the above arguments, the Examiner is respectfully requested to reconsider his position and to timely allow the present application

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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